

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE AND THE
APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
EMERGENCY MEETING

LOCATION: VIA ZOOM

DATE: FRIDAY, MAY 29, 2020
1 P.M.

REPORTER: BETH C. DRAIN, CA CSR
CSR. NO. 7152

FILE NO.: 2020-11

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION:	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
ACTION ITEMS:	
3. CONSIDERATION OF EXISTENCE OF EMERGENCY SITUATION. EMERGENCY SITUATION MEANS ANY OF THE FOLLOWING AS DETERMINED BY A MAJORITY OF THE MEMBERS OF THE ICOC: (A) WORK STOPPAGE OR OTHER ACTIVITY THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH; (B) CRIPPLING DISASTER THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH.	4
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO SPECIAL CALL FOR COVID-19 PROJECTS.	6
CLOSED SESSION:	NONE
5. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 4 ABOVE. (HEALTH & SAFETY CODE 125290.30(F)(3)(B) AND (C)).	
DISCUSSION ITEMS:	
6. PUBLIC COMMENT	NONE
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FRIDAY, MAY 29, 2020; 1 P.M.

CHAIRMAN THOMAS: THANK YOU. WOULD LIKE
TO WELCOME EVERYBODY TO THE MAY 29TH EMERGENCY
MEETING OF THE ICOC AND APPLICATION REVIEW
SUBCOMMITTEE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

DR. DURON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA
PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
QUINT. AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

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MR. SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: DIANE WINOKUR. YOU'RE ON MUTE, DIANE, BUT I SEE YOU. SO I'M GOING TO MARK YOU AS PRESENT.

OKAY. J.T., WE HAVE A QUORUM.

CHAIRMAN THOMAS: THANK YOU, MARIA.

THIS IS THE LATEST IN A SERIES OF MEETINGS WE'VE BEEN HAVING REGARDING COVID-RELATED PROJECTS RECOMMENDED FOR FUNDING BY THE GWG, WHICH THIS WEEK MET ON TUESDAY MORNING.

PROCEEDING TO THE ACTION ITEMS AS BEFORE, FIRST, BEFORE WE GET TO THE ACTUAL PROJECTS, WE NEED TO VOTE ON THE FOLLOWING: CONSIDERATION OF EXISTENCE OF EMERGENCY SITUATION. EMERGENCY SITUATION MEANS ANY OF THE FOLLOWING AS DETERMINED BY A MAJORITY OF THE MEMBERS OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE: A, WORK STOPPAGE OR OTHER ACTIVITIES THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH; B, CRIPPLING DISASTER THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH.

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DO I HEAR A MOTION TO APPROVE?

DR. HIGGINS: YES. THIS IS DAVID. YES.

CHAIRMAN THOMAS: MOVED BY DAVID HIGGINS,
SECONDED, I BELIEVE BY, DAVE, WAS THAT YOU?

DR. MARTIN: YES.

CHAIRMAN THOMAS: BY DR. MARTIN. ANY
DISCUSSION BY MEMBERS OF THE BOARD? ANY DISCUSSION
BY MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL
YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

DR. DURON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA
PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. YOU'RE

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ON MUTE, BUT I SEE YOU. THANK YOU.

ROBERT QUINT. AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD. JONATHAN
THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: THANK YOU. MOTION
CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA.

ON TO ITEM 4, WHICH IS CONSIDERATION OF
APPLICATIONS SUBMITTED IN RESPONSE TO SPECIAL CALL
FOR COVID-19 PROJECTS. I WILL TURN THE MEETING AT
THIS POINT OVER TO MR. SHEEHY.

MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS.
DR. SAMBRANO, DO YOU HAVE A PRESENTATION FOR THIS
ROUND?

DR. SAMBRANO: YES, I DO. THANK YOU, MR.
SHEEHY.

DOUG, DO YOU HAVE THE PRESENTATION TO PUT

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UP, OR WOULD YOU LIKE ME TO DO THAT? THANK YOU.
YOU CAN JUST SKIP OVER TO SLIDE 3.

GOOD AFTERNOON, EVERYONE. SO WE BY NOW
ARE PRETTY FAMILIAR WITH THE COVID-19 PROGRAM.
WE'VE OBVIOUSLY BEEN HEARING QUITE A BIT ABOUT IT
AND JUST HAD A COUPLE OF BOARD MEETINGS ON IT, SO I
WON'T BELABOR THIS.

I DO WANT TO POINT OUT THAT FOR THIS
PARTICULAR CYCLE ALL THE APPLICATIONS THAT CAME IN
AND THAT WERE REVIEWED WERE ALL IN THE DISCOVERY
ARENA, SO THEY WERE ALL DISC2 APPLICATIONS. AND SO
A REMINDER THAT THE AWARD AMOUNT FOR THESE TYPES OF
APPLICATIONS IS 150,000 WITH A DURATION OF UP TO 12
MONTHS. NEXT SLIDE, PLEASE.

THESE ARE THE KINDS OF PROJECTS THAT ARE
INTENDED TO IDENTIFY A CANDIDATE FOR DEVELOPMENT,
EITHER A THERAPEUTIC OR A TOOL OF SOME KIND. AND WE
SET AN AMBITIOUS SIX-MONTH GOAL FOR ALL THESE
PROJECTS, AND IN THIS CASE FOR ALL THE DISC2S TO
HAVE DATA FOR A VIABLE CANDIDATE THAT CAN PROGRESS
QUICKLY TO THE CLINIC. NEXT SLIDE PLEASE.

SO FOR THIS CYCLE THERE WERE 13
APPLICATIONS THAT WERE REVIEWED. THERE WERE THREE
THAT WERE SCORED IN THE FUNDABLE RANGE AND THUS
RECOMMENDED FOR FUNDING. SO THE TOTAL APPLICANT

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REQUESTS WOULD BE 449,000, 450,000 BASICALLY. THERE IS WE STILL 2.9 MILLION AVAILABLE IN THE COVID-19 PROGRAM FUND.

AND SO THE THREE APPLICATIONS THAT ARE RECOMMENDED ARE SHOWN ON THIS TABLE. THE FIRST ONE IS 11947. AND SO THIS IS AN APPLICATION THAT HAD THE SCORE OF 95. AND IT'S ENTITLED "PERSISTENT OFF-THE-SHELF ME-ACE2-CAR-IL15 NK CELLS DERIVED FROM CD34 POSITIVE CORD BLOOD STEM CELLS TO PREVENT AND TREAT COVID-19."

SO WHAT THIS APPLICATION PROPOSES TO DO IS DEVELOP A CELL THERAPY OF NATURAL KILLER CELLS THAT EXPRESS AN ACE2 RECEPTOR, THAT'S THE RECEPTOR THAT THE COVID-19 VIRUS SARS COV2 ATTACHES TO, AS WELL AS IL15 WHICH HELPS THOSE NK CELLS PERSIST. AND SO THEY'VE ENGINEERED THIS CONSTRUCT TO USE AS A CELL THERAPY AND INTEND TO DEVELOP THAT FOR USE IN PATIENTS WITH COVID-19.

THE SECOND APPLICATION IS 11920. THAT ONE RECEIVED A SCORE OF 90, AND IT'S ENTITLED "APPLICATION OF PROSTAGLANDIN E2 AND BPV," WHICH IS A MUSCLE STEM CELL-TARGETING THERAPEUTIC. IT'S A COMBINATION DRUG TO TREAT COVID-19 ASSOCIATED DIAPHRAGM ATROPHY. SO THIS IS FOR PATIENTS SUFFERING FROM VENTILATOR-INDUCED DIAPHRAGMATIC

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DYSFUNCTION OR VIDD.

SO THIS OCCURS IN PATIENTS WHO DEVELOP A COMPLICATION FROM HAVING LONG-TERM MECHANICAL VENTILATION, WHICH HAPPENS TO BE TRUE FOR MANY COVID-19 PATIENTS. AND SO WHAT THIS THERAPEUTIC INTENDS TO DO IS TO INDUCE AND TREAT PATIENTS AND TREAT THE MUSCLE ATROPHY IN THE DIAPHRAGM OF THESE PATIENTS.

AND THEN THE LAST RECOMMENDED APPLICATION IS 11941 THAT GOT A SCORE OF 86. THIS APPLICATION IS ENTITLED "IDENTIFYING HLA CLASS I RESTRICTED PEPTIDES THAT INDUCE CD8-POSITIVE T-CELLS AGAINST SARS COV2."

SO THE GOAL OF THIS PROJECT IS TO IDENTIFY PEPTIDES FROM THE SARS COV2 VIRUS THAT CAN BE UTILIZED AND DEVELOPED AS A VACCINE FOR THE TREATMENT OF COVID-19. AND SPECIFICALLY THEY ARE DEVELOPING PEPTIDES IN A DIFFERENT AND NOVEL WAY THAT CAN INDUCE MOST SPECIFICALLY CD8 POSITIVE T-CELL RESPONSES WHICH ARE BELIEVED TO BE THE MOST LONG LASTING AND PROBABLY THE LIKELIEST MECHANISM TO ALLOW RECOVERY FROM COVID-19.

SO THOSE ARE THE RECOMMENDED APPLICATIONS. AND, DOUG, YOU CAN PUT ON THE SCREEN THE SPREADSHEET THAT SHOWS THE REMAINDER OF THE APPLICATIONS ALONG

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WITH THESE THREE. THAT IS THE CONCLUSION OF MY PRESENTATION, MR. SHEEHY.

MR. SHEEHY: THANK YOU, DR. SAMBRANO.

DR. STEWARD: EXCUSE ME. THIS IS OS. CAN YOU FOLKS HEAR ME?

MR. SHEEHY: YES.

MS. BONNEVILLE: THANKS, OS.

MR. SHEEHY: THANK YOU, DR. SAMBRANO.

SO AT THIS POINT I WILL TAKE A MOTION TO MOVE ANY PROJECTS IN TIER II, THE UNFUNDABLE RANGE, INTO TIER I, THE FUNDABLE RANGE, IF THERE IS SUCH A MOTION. IS THERE A MOTION TO DO THAT?

HEARING NONE, I WILL THEN TAKE MOTIONS ON TIER I. I'M GOING TO STEP FORWARD WITH A LITTLE BIT OF CHAIR PRIVILEGE HERE BECAUSE I DID WANT TO SEPARATE OUT APPLICATION -- I'M TRYING TO FIND THE NUMBER -- 11941 BECAUSE I WOULD LIKE TO MOVE THAT FORWARD FOR FUNDING. BUT I WOULD LIKE TO MOVE THAT FORWARD WITH FUNDING WITH AN AMENDMENT. AND THE AMENDMENT WOULD BE A CONDITION THAT THE APPLICANT TAKE, AND I BELIEVE THE APPLICANT IS ON THIS CALL TODAY, BUT THAT THE APPLICANT ADD WORK OR SHIFT WORK IN ORDER TO TAKE INTO ACCOUNT HLA TYPES FOR POPULATIONS THAT ARE DISPROPORTIONATELY IMPACTED BY COVID.

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IN THE REVIEW THE REVIEWERS NOTED THAT THE HLA TYPES THAT WERE GOING TO BE USED FOR THIS VACCINE WERE FROM WESTERN EUROPE. AS WE ALL ARE WAY TOO PAINFULLY AWARE, THIS COVID PANDEMIC IS DISPROPORTIONATELY AFFECTING CERTAIN COMMUNITIES IN OUR COUNTRY. AND I WILL NOTE THAT THE REVIEWERS EXPRESSED THAT APC'S, WHICH I TAKE TO ME ANTIGEN PRESENTING CELLS, COULD BE GENERATED FOR THESE OTHER HLA TYPES FAIRLY QUICKLY AND IN AS SHORT A TIME AS POTENTIALLY A WEEK. BUT I THINK IF YOU LOOK AT YOUR COMMENTS FROM THE REVIEW IN THE SUMMARY, IN TWO SEPARATE PLACES THEY NOTE THE LACK OF HLA TYPES FROM DISPROPORTIONATELY INFECTED POPULATIONS.

SO WITH THAT CONDITION, I WOULD LIKE TO SEE IF THERE'S A SECOND TO A MOTION TO APPROVE THAT APPLICATION, AND THEN WE CAN DEAL WITH THE OTHER TWO AFTER THAT IF THE REST OF THE BOARD WILL INDULGE ME WITH THAT.

MS. DURON: SECOND.

MS. BONNEVILLE: CAN YOU PLEASE REPEAT THE APPLICATION?

MR. SHEEHY: SECOND BY MS. DURON.

MS. BONNEVILLE: CAN YOU PLEASE LET ME KNOW WHICH APPLICATION NUMBER THIS IS AGAIN? I'M SORRY. I DIDN'T CATCH IT.

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MR. SHEEHY: 11941. IT'S A VACCINE APPLICATION.

MS. BONNEVILLE: THANK YOU.

MR. SHEEHY: IS THERE ANY BOARD DISCUSSION ON THIS MOTION?

MR. TORRES: THE VACCINE ISSUE IS RELATED TO STEM CELLS, RIGHT?

MR. SHEEHY: PARDON ME?

MR. TORRES: THE VACCINE ISSUE IS RELATED TO STEM CELLS.

MR. SHEEHY: I SUPPOSE. I MEAN THEY DID MAKE THE COMMENT IN REVIEW THAT AIM 3, WHICH WAS THE WEAKEST AIM, WAS THROWN IN TO MAKE IT RELEVANT IN STEM CELLS.

MR. TORRES: I JUST WANT TO MAKE SURE WE ARE CONSISTENT WITH THE BOARD POLICY WE ADOPTED RECENTLY.

MR. SHEEHY: YEAH. I ALSO NOTE THAT REVIEWERS FELT THAT THIS WAS A VERY IMPORTANT PROJECT BECAUSE THERE ABSOLUTELY IS A NEED, ACCORDING TO REVIEWERS, FOR BACKSTOP VACCINES IF CURRENT PROJECTS DON'T SUCCEED, AND THIS IS AN INCREDIBLY NOVEL APPROACH AND KIND OF WHAT WE WERE TRYING TO GET AT LAST WEEK. IN ANY EVENT, IS THERE ADDITIONAL BOARD COMMENT?

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MR. TORRES: AT THE END OF THE DAY, IF WE APPROVE THIS PROJECT AND IT TURNS OUT THAT THEY DID NOT USE STEM CELL RESEARCH, WILL THAT VIOLATE THE BOARD'S ACTION WE TOOK LAST WEEK?

MR. SHEEHY: THE BOARD FAILED TO TAKE ANY ACTION LAST WEEK, SENATOR TORRES. AND AS I STATED, AIM 3 DOES INDEED USE STEM CELLS AS PART OF THE PROJECT.

MR. TORRES: I BEG TO DIFFER. WE ACCEPTED A MOTION TO MAKE IT CLEAR THAT ANY VACCINE RESEARCH WOULD BE RELATED TO STEM CELLS; IS THAT CORRECT, GILBERT?

MR. SHEEHY: I THOUGHT THAT WE DID NOT ACCEPT A MOTION TO DO A VITAL RESEARCH OPPORTUNITY. I DON'T THINK WE THEN CHANGED ANYTHING OTHER THAN WHAT WE'VE CURRENTLY BEEN DOING.

DR. SAMBRANO: THIS APPLICATION IS ELIGIBLE AND FITS WITHIN OUR CURRENT ELIGIBILITY CRITERIA. IT INCLUDES THE USE OF STEM CELLS AND SO, THEREFORE, IT IS ONE WE COULD FUND.

MR. TORRES: RIGHT. WHICH WE AFFIRMED LAST WEEK. OKAY. THANK YOU.

DR. DURON: MAY I MAKE A COMMENT?

MR. SHEEHY: PLEASE.

DR. DURON: I APPRECIATE THAT YOU BROUGHT

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THIS UP BECAUSE IN MY READ I WAS TRYING TO LOOK FOR SOME RECOMMENDATION, NOT NECESSARILY UNDERSTANDING TOTALLY WHERE SUCH A RECOMMENDATION FOR PROPORTIONAL AND EQUITABLE RESEARCH IS REQUIRED, WHERE WE HAVE TO MAKE AN AMENDMENT, WHERE WE NEED TO BRING THE RESEARCHER IN FOR THE TALK. SO I APPRECIATE THAT YOU RECOGNIZE THIS, AND I WOULD HOPE THAT SOMEHOW WE DON'T HAVE TO KEEP DOING THIS, BUT THAT THIS CAN BE A VERY INCLUSIVE EITHER AMENDMENT OR ONE OF THE REQUIREMENTS OF ANY AND ALL RESEARCH PROPOSALS THAT QUALIFY OR THAT HAVE TO USE THIS STANDARD, THAT IT BE PROPORTIONATE AND INCLUSIVE OF UNDERSERVED COMMUNITIES.

IT'S NO LONGER JUST A FRIENDLY AMENDMENT, BUT THAT IT IS A PART OF THE INITIAL RESEARCH PROPOSAL. I DON'T KNOW, AS I SAID, IF THAT'S LIMITED OR IT CAN APPLY ACROSS THE BOARD FOR EVERYTHING FROM DISCOVERY TO CLINICAL TRIALS.

MR. SHEEHY: THANK YOU, MS. DURON. I SECOND YOUR WISH. AND PERHAPS THIS IS SOMETHING, I'M SURE, THAT THE CHAIR MIGHT POTENTIALLY TAKE FORWARD IN THE FUTURE. BUT I THINK THIS IS A GOOD THING FOR THE CIRM TEAM TO WORK ON BECAUSE I WAS SOMEWHAT STRUCK WHEN REVIEWERS LOOKING AT THE PROJECT, IT WAS GLARING, FRANKLY, THE MISMATCH

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BETWEEN THE POPULATION THAT HAS BEEN SO DISPROPORTIONATELY IMPACTED IN THE UNITED STATES BY THIS EPIDEMIC AND THE HLA TYPES THAT THEY WERE USING IN ORDER TO DERIVE THIS VACCINE.

I DON'T THINK THAT THERE'S ANYTHING -- ANY BAD INTENT ON RESEARCHERS' PART, BUT I DO THINK IT'S IMPORTANT THAT WE CALL THIS OUT AND LET THE COMMUNITY KNOW THAT THIS IS IMPORTANT TO US AND A KEY VALUE FOR CIRM GOING FORWARD.

DR. STEWARD: COULD I MAKE A COMMENT?

MR. SHEEHY: PLEASE.

DR. STEWARD: SO I TOTALLY SUPPORT THE SENTIMENT AND THE MOTION IN THIS CASE. THE ONE PROBLEM IS THAT WE'VE ALWAYS HELD TO THE CONCEPT THAT WE SHOULD NOT REWRITE THE APPLICANTS' GRANTS. I THINK THIS BORDERS ON DOING THAT A BIT AND THAT IT DOES IMPACT A BIT ON REVIEW. SO THE MORE BREADTH YOU TAKE, THE LESS STEPS. AND REVIEWERS OFTEN CRITICIZE APPLICATIONS FOR TRYING TO BE TOO BROAD AND, THEREFORE, NOT BEING ABLE TO ACCOMPLISH WHAT THEY SET OUT TO DO. I RAISE ALL THIS NOW BECAUSE GOING FORWARD I THINK IT'S GOING TO BE IMPORTANT. THANK YOU.

MR. SHEEHY: THANK YOU, DR. STEWARD.

IS THERE ADDITIONAL BOARD COMMENT?

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MR. JUELSGAARD: SO COULD WE HEAR THE FACTS, THOUGHTS ABOUT YOUR PROPOSED AMENDMENT?

MR. SHEEHY: PARDON ME?

MR. JUELSGAARD: WELL, WE'VE HEARD FROM YOU ABOUT YOUR PROPOSED AMENDMENT AND YOUR CONCERNS. I'D LIKE TO HEAR FROM SOMEBODY FROM STAFF.

MR. SHEEHY: OH, FROM THE STAFF. I'M SORRY. I DIDN'T HEAR THAT. YEAH, PLEASE. DR. SAMBRANO.

DR. SAMBRANO: SURE. I MEAN THOSE ARE AMENDMENTS WE CAN CERTAINLY MAKE. I THINK THE ONLY COMMENTS I WOULD HAVE IS THAT FOR EARLY STAGE DISCOVERY WORK, TYPICALLY THE WORK IS BROADLY APPLICABLE IN MOST CASES, BUT I THINK WE CAN CERTAINLY MAKE AN AMENDMENT IN AN APPLICATION LIKE THIS IN ORDER TO ADJUST IT AS REQUESTED.

I THINK THE APPLICANT MAY BE ON THE LINE AS WELL AND MIGHT BE ABLE TO SPEAK TO THE FEASIBILITY OF DOING SO, BUT I THINK IT IS SOMETHING THAT IS CERTAINLY DOABLE.

MS. BONNEVILLE: I DO BELIEVE THE APPLICANT IS ON THE LINE.

MR. SHEEHY: IF THE APPLICANT WOULD LIKE TO MAKE A COMMENT TO THAT. I JUST, AGAIN, NOTE THAT THE REVIEWERS --

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DR. WONG: IT IS ALBERT WONG. I AM THE PI FOR THAT PARTICULAR PROPOSAL. AND, WELL, FIRST OF ALL, WE'RE WORKING, AS DR. SAMBRANO MENTIONED, ON A MAJOR HLA ALLELE. YES, IT'S PRESENT WESTERN POPULATION, BUT THAT PARTICULAR ALLELE IS ALSO PRESENT IN MANY OF THE POPULATIONS AFFECTED BY COVID-19. SO IT DOESN'T EXCLUDE THEM. THAT'S FOR SURE.

ALSO, THERE IS OVERLAP BETWEEN PEPTIDES THAT BIND TO HLA-A2. AND I JUST CALLED UP THE COMMON HLA ALLELE IN AFRICAN-AMERICANS AS WELL AS HISPANICS AND ASIAN POPULATIONS. SO THERE IS OVERLAP BETWEEN PEPTIDES THAT BIND TO HLA-A2 AND HLA-30-01, 29-02, WHICH IS PRESENT IN THE HISPANIC POPULATION. THE FIRST ALLELE, 30-01, IS PRESENT IN THE AFRICAN-AMERICAN POPULATION. AND THEN 02-07 IN THE ASIAN POPULATION IS ACTUALLY EXTREMELY SIMILAR IN ITS BINDING TO HLA-02-01. SO I WOULD EXPECT PERFECT CONCORDANCE BETWEEN THE ASIAN POPULATION AND THE HLA-A2 POPULATION.

HOWEVER, AS WAS MENTIONED IN THE REVIEW, IT IS FEASIBLE TO TAKE THOSE CELLS FROM TYPE 2 POPULATIONS FROM THE STANFORD BLOOD BANK AND GENERATE THE STEM CELLS AS WE CONTEMPLATE IN OUR PROPOSAL IN ORDER TO CREATE THIS AUTOLOGOUS SYSTEM

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AND ANALYZE IT FOR BINDING. IT IS MORE WORK THOUGH. CERTAINLY WE CAN DO IT. WE CERTAINLY CAN ACCOMMODATE IT. I WAS GOING TO SPEAK DURING THE PUBLIC COMMENT SESSION. WE CAN CERTAINLY ACCOMPLISH THIS WORK. I THINK ONE REVIEWER DID NOTE IN OUR REVIEW THAT IT'S AMBITIOUS WORK, AND THAT PERSON DID THINK THAT WE ACCOMPLISHED IT.

BUT I DO NOTE THAT THE ICOC DID APPROVE FOR APPLICATIONS GOING FORWARD A DISCOVERY 2 BUDGET OF 250,000. CERTAINLY WE COULD ACCOMMODATE MANY, MANY -- ANALYSIS OF MANY, MANY MORE ALLELES IN OUR STUDIES IF WE DID HAVE MORE SUPPLY MONEY AVAILABLE FOR OUR RESEARCH. SO I'LL STOP AND TAKE THE COMMENTS FROM THERE.

MR. SHEEHY: THANK YOU. SO ANY ADDITIONAL BOARD COMMENTS OR QUESTIONS?

DR. DURON: IF NOBODY ELSE HAS ANYTHING TO SAY.

CHAIRMAN THOMAS: I'LL GO AFTER YOU, YSABEL.

DR. DURON: THANK YOU, J.T. I APPRECIATE, I BELIEVE YOU SAID DR. WONG, I APPRECIATE WHAT HE SAID. WHAT MY CONCERN IS AND WHAT I HAVE SEEN IN RESEARCH GRANT AFTER RESEARCH GRANT IS THERE IS MORE OF AN ASSUMPTION THAT THERE WILL BE INCLUSION AS

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OPPOSED TO A REALITY OF TOO MANY TIMES, PARTICULARLY FOR COMMUNITIES OF COLOR, WE SEE A PROMISE OF DELIVERY, BUT WE DON'T FEEL OR SEE A RESULT.

AND I THINK THAT FOR GOING FORWARD, I WOULD LIKE TO SEE THAT IT IS SPECIFICALLY ADDRESSED, THAT COMMUNITIES OF COLOR ARE INCLUDED IN THE RESEARCH AND THAT THERE ARE WAYS IN WHICH THIS IS ACTUALLY SHOWN ON THE OTHER END THAT IN FACT THEY WERE INCLUDED BECAUSE I THINK THIS IS IMPORTANT SYMBOLICALLY FOR MANY COMMUNITIES WHO HAVE FELT EXCLUDED FROM RESEARCH AND WHO OFTENTIMES FEEL USED BUT NOT SERVED.

AND SO WHILE I THINK IN SOME WAYS IT COULD BE JUST SYMBOLIC, BUT I WOULD LOVE FOR IT TO BE VERY CLEAR, VERY PLAIN, AND PUTS US RIGHT THERE AT THE, I THINK, THE LEADING EDGE CALLING ON RESEARCHERS TO MAKE THIS VERY CLEAR AND VERY PLAIN THAT WE ARE LOOKING TO SERVE THE UNDERSERVED AND THE UNDERRESEARCHED.

OBVIOUSLY WE DON'T AND I DON'T KNOW ALL OF THE INS AND OUTS OF THE SCIENCE ITSELF. SO AS YOU EXPLAIN THINGS, I'M GOING, OH, AHA. THAT'S GOOD. BUT I DO BELIEVE THAT WE NEED TO MAKE IT VERY CLEAR AND PLAIN TO THE PUBLIC WHAT WE ARE DOING AND THAT IT'S INCLUSIVE. AND THEN MAYBE AT SOME POINT IN

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TIME I CAN STOP HARPING ON THIS SAME ISSUE. BUT RIGHT NOW FOR ME IT STILL FEELS LIKE WE'RE MAKING ASSUMPTIONS THAT RESEARCH WILL DO WHAT IS RIGHT AS OPPOSED TO NOW REQUIRING THAT THEY DO WHAT IS RIGHT. AND SO I STAND ON THE SIDE OF REQUIRE TO DO WHAT IS RIGHT. THANK YOU.

MR. SHEEHY: THANK YOU, MS. DURON.

CHAIRMAN THOMAS.

CHAIRMAN THOMAS: YES. I WOULD LIKE TO SUPPORT THE MOTION AS WELL. I THINK THAT THE COMMENTS THAT MS. DURON HAS MADE AS WELL AS OTHERS, WE'VE NOW BEEN ADDRESSING AND COMMENTING ON THE NEED TO ADHERE TO THESE SUGGESTIONS IN GENERAL, BUT PARTICULARLY HERE WHERE YOU DO HAVE A DISPROPORTIONATE IMPACT ON CERTAIN COMMUNITIES AND YOU WANT TO MAKE SURE TO THE FULL EXTENT POSSIBLE THAT WORK BEING DONE IS GOING TO ADDRESS THE NEEDS OF THOSE COMMUNITIES. SO I WHOLEHEARTEDLY AGREE.

GIL, I WANTED TO ASK YOU A QUESTION ABOUT DR. WONG HAS MENTIONED THE BUDGET ISSUE HERE. OBVIOUSLY WE HAVE NO FIGURES THAT ADDRESS THE INCREASE OF THE BUDGET TO ACCOMMODATE IT UP TO THE TWO FIFTY OR WHATEVER. COULD YOU JUST RESPOND TO HIS COMMENTS PLEASE ON THAT POINT?

DR. SAMBRANO: SO EVERYONE THAT IS COMING

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IN AT THE MOMENT IS BOUND BY THE CONCEPT AS IT EXISTED WHEN THEY APPLIED. SO MEANING THAT THE LIMIT OF THEIR BUDGET IS A HUNDRED FIFTY THOUSAND. AND SO THE ACTIVITIES THAT ARE PROPOSED SHOULD FIT WITHIN THAT BUDGET.

IF THERE ARE ADDITIONAL EXPERIMENTS OR ACTIVITIES, CERTAINLY APPLICANTS HAVE TO APPLY AGAIN AND ASK FOR ADDITIONAL FUNDS. SO A WAY OF EXCEEDING THE AMOUNT ON A GIVEN PROJECT.

MR. SHEEHY: PERHAPS CHAIRMAN THOMAS CAN MAKE AN AMENDMENT TO MY AMENDMENT INCREASING THE BUDGET, SAY, UP TO ANOTHER 100,000 SINCE THE APPLICANT DID MENTION THE \$250,000 LIMIT IN ORDER TO DO THE WORK TO MAKE SURE THAT THE HLA-A IS REPRESENTATIVE OF THE COMMUNITIES MOST DISPROPORTIONATELY IMPACTED BY THE PANDEMIC AND THAT THE DECISION ON HOW MUCH FUNDS AND HOW THEY ARE RELEASED WITH THE CIRM TEAM.

SO, FOR INSTANCE, DR. SAMBRANO, DR. WONG WOULD BRING TO YOU A SUGGESTED BUDGET IN ORDER TO COVER ALL OF THE HLA TYPES THAT ARE NOT COVERED AS HE JUST DESCRIBED GOING TO THE STANFORD BLOOD BANK. AND WHATEVER THAT NUMBER IS, 5,000, 50,000, WHAT HAVE YOU, THAT THE CIRM TEAM COULD NEGOTIATE THAT WITH HIM. SEEMS LIKE A VERY STRAIGHTFORWARD, SIMPLE

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THING TO BE DONE TO MAKE SURE THAT WE ARE ACTUALLY DEVELOPING A VACCINE THAT WILL BE AVAILABLE FOR COMMUNITIES THAT HAVE BEEN OVERWHELMINGLY DISPROPORTIONATELY IMPACTED.

DR. STEWARD: BEFORE THERE'S A MOTION, COULD I MAKE A COMMENT ABOUT THE GENERAL CONCEPT?

MR. SHEEHY: I THINK CHAIRMAN THOMAS WAS COMING IN, AND THEN I'LL HEAR FROM YOU.

CHAIRMAN THOMAS: THAT'S FINE. I DEFER TO DR. STEWARD.

DR. STEWARD: I WANTED TO ACTUALLY SAY THIS BEFORE J.T. MADE THE MOTION BECAUSE I THINK IT'S AN IMPORTANT POINT TO CONSIDER. SO WE ARE KIND OF DOING THINGS ON THE FLY HERE. AND AS EVERYBODY KNOWS, I'M PRETTY MUCH A PROCEDURE GUY. AND IT WORRIES ME THAT WE ARE TRYING TO DO THINGS WITHOUT ACTUALLY HAVING SEEN, FOR EXAMPLE, AN APPLICATION FOR HOW THESE FUNDS WOULD BE USED AND HAVING THAT REVIEWED BY THE GRANTS WORKING GROUP.

I'M SURE ANY OF THE OTHER APPLICANTS TO THIS CURRENT ROUND COULD EASILY JUSTIFY THE BUDGET OF \$250,000. I GUARANTEE IT. AND THEY COULD HAVE EXPANDED TO MAKE SURE THAT THEY HAD SECTIONS ON INCLUSIVITY. I THINK IT'S UNFAIR TO THE OTHER APPLICANTS TO DO THIS IN AN AD HOC WAY. AS GIL

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SAID, IT'S POSSIBLE FOR THIS APPLICANT, DR. WONG, TO COME BACK AT ANY TIME TO REQUEST ADDITIONAL FUNDS. IT'S VERY EASY TO DO. I'D RATHER DO IT SYSTEMATICALLY THAN AD HOC. THANK YOU.

MR. SHEEHY: DR. STEWARD, I TAKE YOUR POINT. I GUESS I'M SITTING HERE IN THE BAY AREA, AND I'M STRUCK THAT WE'VE DONE COMMUNITYWIDE TESTING IN TWO DIFFERENT AREAS VIA UCSF. AND THE OVERWHELMINGLY WHITE COMMUNITY OF GALENAS, WE WERE UNABLE TO IDENTIFY A SINGLE INFECTION. YET IN AN AREA OF THE MISSION, PREDOMINANTLY HISPANIC NEIGHBORHOOD, 95 PERCENT OF THE INFECTIONS WERE IDENTIFIED IN LATINOS. THESE KINDS OF DISPARITIES EXIST UP AND DOWN THE STATE AND ACROSS THE COUNTRY.

AND I AGREE THAT THIS IS AN UNUSUAL CIRCUMSTANCE; BUT, FRANKLY, OUR RESPONDING TO COVID IS AN UNUSUAL CIRCUMSTANCE. AND I THINK IF WE ARE INTENT ON RESPONDING TO COVID, I THINK WE NEED TO, NO. 1, EXHIBIT A SENSE OF URGENCY FOR COMMUNITIES AND INDIVIDUALS WHO ARE CONFRONTED BY THIS DISEASE DIRECTLY, AND I THINK A LITTLE BIT OF FLEXIBILITY IN AN AGENCY THAT'S SPENT ALMOST \$3 BILLION AT THIS POINT OVER 50 TO A \$100,000 SEEMS RATIONAL IN THE FACE OF A GLOBAL PANDEMIC.

MS. BONNEVILLE: I BELIEVE DR. MARTIN ALSO

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HAS A COMMENT.

MR. SHEEHY: SURE, DR. MARTIN.

DR. MARTIN: I HAVE A QUESTION. JEFF, YOUR MOTION, THE SPECIFICS OF YOUR MOTION I WOULD BE INTERESTED IN BECAUSE WE HEARD FROM DR. WONG THAT THE HLA-A2 ALLELE IS CURRENTLY REPRESENTED BY, I RECALL HE SAID, THE HISPANIC POPULATION. THE FACT THAT IT'S HIGH IN THE WESTERN EUROPEAN IS NOT SO RELEVANT TO ME AS WHETHER THE UNDERPRIVILEGED, HIGHLY VULNERABLE POPULATION IS NOT ADEQUATELY REPRESENTED BY THE HLA-2 HAPLOTYPE.

AND SO I WONDER WHETHER IT COULD BE -- I DON'T REMEMBER EXACT WORDS OF YOUR AMENDMENT, BUT COULD IT BE REWORDED SUCH THAT THEY WERE NOT DISADVANTAGED BY THE PRIMARY FOCUS OF THIS RESEARCH GRANT IN TERMS OF THE PREVALENCE OF THE HLA-A2 ALLELE?

MR. SHEEHY: I SUPPOSE. AND I JUST WOULD LIKE TO REMARK THAT I'M OPERATING OFF CONCERNS THAT WERE EXPRESSED BY SEVERAL REVIEWERS IN THE GWG. THIS IS NOT A FIELD WHERE I OBVIOUSLY HAVE THE DEPTH OF KNOWLEDGE TO BE ABLE TO DESCRIBE WHAT IT TAKES TO MAKE SURE THAT THIS PROJECT WOULD COVER POPULATIONS DISPROPORTIONATELY IMPACTED BY COVID. AND PERHAPS, DR. WONG -- WOULD THAT HELP, DR. MARTIN, TO HEAR

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FROM DR. WONG AGAIN IF HE'S STILL WITH US?

DR. MARTIN: YES. IT CERTAINLY WOULD.
THAT WOULD HELP.

DR. WONG: I'M ON THE LINE. GO AHEAD.

MR. SHEEHY: PLEASE.

DR. MARTIN: MY QUESTION SIMPLY, DR. WONG,
IS IS THE HLA-A2 HAPLOTYPE UNDERREPRESENTED IN THE
POPULATIONS AND PARTICULARLY CALIFORNIA THAT ARE
DISPROPORTIONATELY INFECTED BY COV2?

DR. WONG: WELL, ACTUALLY FIRST OF ALL,
HLA ALLELE TYPE AFFECTED BY COVID-19 IS ACTUALLY ONE
OF MY PET INTERESTS BECAUSE I AM QUITE AWARE OF HOW
DIFFERENT POPULATIONS HAVE BEEN AFFECTED. THIS IS
WHY I HAVE THIS INFORMATION RIGHT IN FRONT OF ME.

SO AS FAR AS HLA-02-01, IN THE
AFRICAN-AMERICAN POPULATION, IT IS THE TENTH MOST
COMMON -- ACTUALLY WHAT I'VE GOT IS THE DUAL ALLELE
TYPE. BUT FOR THE 02-01 ALLELE, WHICH IS WHAT WE'RE
LOOKING AT PRIMARILY FOR THIS APPLICATION, IT IS
HIGHLY REPRESENTED.

I WANT TO SAY APPROXIMATELY 30 PERCENT OF
AFRICAN-AMERICANS WOULD HAVE IT. IT IS THE TENTH
MOST REPRESENTED ALLELE WHEN CONSIDERED WITH THE
HLA-B SUBTYPE. IN THE ASIAN-AMERICAN POPULATION, IT
IS THE SECOND MOST COMMON ALLELE TYPE. AND IN THE

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HISPANIC POPULATION, IT IS THE -- AGAIN, IT'S THE NINTH MOST COMMON ALLELE TYPE. SO THERE IS REPRESENTATION THERE OF THOSE POPULATIONS THAT ARE DISPROPORTIONATELY AFFECTED BY COVID-19.

AND, ALSO, I DO EXPECT THAT PEPTIDES THAT BIND TO HLA-A2 WILL ALSO BIND TO THE COMMON ALLELES FOUND IN THESE OTHER POPULATIONS BECAUSE THERE HAS TO BE OVERLAP. WE DO REACT VERY SIMILARLY TO ANTIGENS. AND SO I WOULD NOT BE SURPRISED IF, ONCE WE'VE DELVED INTO IT AND LOOKED AT IT, THAT WE WOULD FIND SOME COMMONALITIES.

BUT CERTAINLY ADDRESSING THAT POPULATION DIRECTLY WOULD BE THE MOST EFFICIENT. I UNDERSTAND THE CONCERNS THAT THERE'S BEEN NO FORMAL VETTING OF ANY BUDGET, BUT CERTAINLY WE COULD SUBMIT A BUDGET PROPOSAL RELATED TO HOW WE COULD EXPAND OUR WORK. AND I WOULD BE MORE THAN HAPPY TO LOOK AT IT. AS I SAID, I DO BELIEVE THAT HLA SUBTYPE IS ONE OF THE UNDERLYING PREDISPOSITIONS TO COVID-19. AND I WOULD BE MORE THAN HAPPY TO INVESTIGATE THAT IN MY LAB.

DR. STEWARD: SO THIS IS OS. AGAIN, COULD I RESPOND TO DR. WONG'S COMMENT AND SUGGESTION THERE BECAUSE I THINK THERE MAY BE SORT OF A MIDDLE GROUND HERE.

AGAIN, WHAT I WAS OBJECTING TO WAS SORT OF

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AN AD HOC ADDITION OF \$100,000 TO A BUDGET THAT HADN'T BEEN REVIEWED BY THE GRANTS WORKING GROUP. IF WE WERE TO CONSIDER A MOTION, I WOULD BE MUCH MORE FAVORABLE, I'M NOT SURE I'D VOTE FOR IT YET, BUT I'D AT LEAST BE MORE FAVORABLE IF THE PROPOSAL WAS TO SUBMIT AN AMENDMENT FOR ADDITIONAL BUDGET THAT WOULD BE REVIEWED BY THE GRANTS WORKING GROUP. THE GWG IS MEETING QUITE OFTEN, REGULARLY; AND SO HAVING THIS CONSIDERATION COULD BE DONE IN A MATTER OF WEEKS AND THEN COULD COME BACK TO THE BOARD FOR FORMAL APPROVAL AS SUCH. THANK YOU.

CHAIRMAN THOMAS: SO, MR. SHEEHY.

MR. SHEEHY: YES, CHAIRMAN THOMAS.

CHAIRMAN THOMAS: SO I'M VERY MINDFUL OF OS' PROCEDURAL POINTS. I AM, HOWEVER, VERY MINDFUL THAT IN MAKING THIS AWARD WE WANT TO MAKE SURE THAT, AS IT'S DEFINED AT THE MOMENT, IT MEETS THE GOALS AS DISCUSSED BY MS. DURON AND OTHERS. AND IF WE APPROVE THIS AND IT GOES -- AND WE HAVE, SAY, AN AMENDMENT OF THE SORT THAT OS JUST PROPOSED AND IT GOES TO THE GWG, AND FOR WHATEVER REASON IT DOES NOT PASS THERE, THEN IF WE VOTE ON THIS PROJECT TODAY, WHICH I AM IN FAVOR OF, WE MAY FIND OURSELVES IN THE SITUATION WHERE WE HAVEN'T ADEQUATELY COVERED THE SCOPE OF WHAT WE WANTED DONE IN THE AWARD AS WE ARE

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VOTING TODAY.

SO I'M A LITTLE -- OS, ARE YOU SUGGESTING THAT WE APPROVE THIS TODAY AND THEN TAKE AN AMENDMENT TO THE GWG, OR ARE YOU PROPOSING THAT WE DON'T APPROVE THIS PENDING A REVIEW OF AN AMENDMENT?

DR. STEWARD: NO. I'M PROPOSING THAT WE APPROVE IT, THAT DR. WONG BE ASKED TO SUBMIT WHAT NIH WOULD CALL A SUPPLEMENTAL APPLICATION. IT IS ALREADY A LITTLE BIT OUT OF OUR NORMAL MODE OF OPERATION, BUT I THINK SOMETHING THAT IS AT LEAST IN KEEPING WITH OUR GENERAL CONCEPT OF THE PROCEDURAL REVIEWS. THAT COULD BE REVIEWED BY THE GWG AND COME BACK TO US AT THE NEXT ARS SUBCOMMITTEE MEETING. THANK YOU.

CHAIRMAN THOMAS: I BELIEVE THAT, GIL, THE NEXT GWG IS A WEEK FROM TUESDAY; IS THAT CORRECT?

DR. SAMBRANO: YES, THAT'S CORRECT.

CHAIRMAN THOMAS: OKAY. I THEN WOULD MOVE THAT WE DO APPROVE THIS TODAY SUBJECT TO OS' AMENDMENT TO HAVE DR. WONG SUBMIT AN AMENDMENT TO THE BUDGET TO THE GWG FOR REVIEW AT THE NEXT MEETING.

MR. SHEEHY: CHAIRMAN THOMAS, WE DO HAVE A PRIOR MOTION. SO AS THE MAKER OF THE MOTION, I WOULD BE WILLING -- I THINK MS. DURON WAS THE SECOND

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TO THAT MOTION. SO THE QUESTION IS IS WHETHER WE WOULD BE WILLING TO ACCEPT THAT AS AN AMENDMENT TO OUR MOTION, I BELIEVE, IS PROBABLY AN APPROPRIATE WAY TO GO. MS. DURON?

DR. DURON: MR. SHEEHY, FIRST OF ALL, I APPRECIATE PROCEDURE AND PROCESS, ET CETERA. SO I'M PERFECTLY OPEN TO AN AMENDMENT. I'M HOPING THAT IN THE FUTURE ALL OF THESE KINDS OF AMENDMENTS CAN BE AVOIDED IF THE CALL FOR PROPOSAL IS VERY CLEAR AT EACH STAGE AND HAS SOME KIND OF REQUIREMENT OF THE RESEARCHERS TO PRESENT THEIR PLANS FOR INCLUSION, ET CETERA. BUT IN THE MEANTIME, I WILL GO ALONG WITH HOW YOU RESTATE THE PROPOSAL, THE AMENDMENT.

MR. SHEEHY: OKAY. SO WHAT I'M PROPOSING, THEN, IS THAT WE ACCEPT CHAIRMAN THOMAS' AMENDMENT TO OUR AMENDMENT TO OUR MOTION TO APPROVE THIS. AND SO THE MOTION WOULD BE TO APPROVE 11941 WITH A CONDITION THAT DR. WONG BRING EXPEDITIOUSLY TO THE GRANTS WORKING GROUP, TO CIRM A REQUEST FOR SUPPLEMENTAL FUNDING IN ORDER TO COMPLETE THE HLA WORK NECESSARY TO MAKE SURE THAT WE CAPTURE -- THAT WE ARE INCLUSIVE IN THE DEVELOPMENT OF THIS PRODUCT TO THE COMMUNITIES THAT HAVE BEEN DISPROPORTIONATELY IMPACTED BY COVID. I THINK THAT'S AGREEABLE TO EVERYONE.

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MR. TORRES: SO WHAT HAPPENS TO THE FIRST TWO APPLICATIONS? ARE THEY INCLUDED IN YOUR MOTION SO WE CAN HANDLE IT ALL IN ONE MOTION?

MR. SHEEHY: IF YOU WOULD LIKE TO DO THAT, WE COULD INCLUDE THOSE TWO AS WELL, SENATOR TORRES. I'M HAPPY TO DO THAT.

MR. TORRES: GREAT.

MR. SHEEHY: IS THERE ANY OBJECTION FROM ANY OF THE OTHER BOARD MEMBERS? MS. DURON, DO YOU MIND IF WE INCLUDE THE OTHER TWO -- GO AHEAD AND FUND THE ONES THAT ARE FUNDABLE SINCE I THINK YOU ARE THE SECOND TO THE ORIGINAL MOTION?

DR. DURON: NO, I DO NOT MIND.

MR. SHEEHY: WITH THAT, IS THERE ANY BOARD DISCUSSION TO THE APPROVAL OF ALL THREE APPLICATIONS IN TIER I? IS THERE ANY PUBLIC COMMENT? MS. BONNEVILLE, COULD YOU CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES, I APPROVE.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELGAARD.

MR. JUELGAARD: YES.

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MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA
PADILLA. ADRIANA, ARE YOU ON THE LINE AND I JUST
CAN'T HEAR YOU, OR DID YOU DROP OFF? LET ME LOOK.

DR. PADILLA: CAN YOU HEAR ME?

MS. BONNEVILLE: OH, NOW I CAN.

DR. PADILLA: YES.

MS. BONNEVILLE: THANK YOU. JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT. AL
ROWLETT.

MR. ROWLETT: YES, AND THANK YOU FOR THE
DISCUSSION.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART.

MR. TORRES: AYE.

MS. BONNEVILLE: DIANE WINOKUR. LET ME

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SEE. DIANE IS ON MUTE, BUT I'M GOING TO SEE IF I CAN -- DIANE, YOU'RE ON MUTE. CAN YOU UNMUTE YOURSELF? SORRY. YES. OKAY. I SEE THE THUMB. THANK YOU.

MOTION CARRIES.

MR. SHEEHY: GREAT. WE HAVE ONE LAST MOTION, AND THAT MOTION WOULD BE NOT TO FUND ANY OF THE APPLICATIONS IN TIER II. DO I HAVE SECOND?

DR. PRIETO: SECOND.

MR. SHEEHY: SECOND BY DR. PRIETO. ANY DISCUSSION BY THE BOARD? ANY PUBLIC COMMENT?

MS. BONNEVILLE: I BELIEVE THERE WAS PUBLIC COMMENT. DOUG, DID YOU SEE -- I THOUGHT I SAW A HAND RAISED.

DR. SNYDER: EVAN SNYDER PLEASE.

MS. BONNEVILLE: OKAY.

MR. SHEEHY: DR. SNYDER.

DR. SNYDER: IS IT MY TURN? ARE YOU READY FOR ME TO GO?

MR. SHEEHY: YES, AND THREE MINUTES PLEASE.

DR. SNYDER: OKAY. I CERTAINLY WILL DO THAT.

I THINK, AS YOU CAN SEE, WE ARE RIGHT ON THE BORDERLINE. AND APROPOS TO THE CONVERSATION WE

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JUST HAD, I THINK THIS IS EXTREMELY PERTINENT.

SO BY QUICK WAY OF BACKGROUND, OUR INSTITUTE, THANKS TO SUMIT CHANDA, DID AN UNBIASED, HIGH THROUGHPUT SCREEN OF 12,000 FDA APPROVED AND CLINICAL STAGE DRUGS AND CAME DOWN TO A LIST OF 30, AND FROM THAT LIST TO SIX THAT CLEARLY INHIBIT THE CYTOPATHIC EFFECTS OF SARS-COV2. HOWEVER, AS YOU KNOW, ALL OF THESE HIGH THROUGHPUT SCREENS ARE DONE ON CLINICALLY IRRELEVANT CELLS. WHAT WE HAVE IS SOMETHING CALLED A LUNG ORGANOID SYSTEM.

MR. TORRES: EXCUSE ME. DR. SNYDER, WE DON'T KNOW WHAT ITEM YOU'RE REFERRING TO. WHAT IS THE NUMBER OF THE GRANT?

DR. SNYDER: I'M SORRY. IT'S THE FIRST -- IT'S THE SECOND ONE. 11782.

MR. TORRES: THANK YOU.

DR. SNYDER: OKAY. AND IT'S A VERY LONG TITLE, BUT PRETTY SELF-EXPLANATORY.

ANYWAY, AS YOU KNOW, THERE IS NO GOOD ANIMAL MODEL; HOWEVER, MOST OF THESE DRUGS HAVE ALREADY NOT ONLY BEEN IN ANIMALS, BUT ALREADY IN HUMANS. THERE IS IN MANY OF THEM A COMPLETE IND PACKAGE IN THE FDA. WHAT IS NEEDED IS SIMPLY A CLINICALLY RELEVANT SYSTEM TO HELP PRIORITIZE THOSE DRUGS TO FAST TRACK TO CLINICAL TRIALS. AND IQVIA

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IS HELPING WITH THIS.

THIS LUNG ORGANOID SYSTEM IS ACKNOWLEDGED BY THE STUDY SECTION AS BEING NOVEL AND POWERFUL. IT HAS ALL OF THE CELL TYPES FOR PROXIMAL AND DISTAL, IT'S INVESTED WITH MACROPHAGES WHICH MEDIATE INFLAMMATORY REACTION IN CYTOKINE STORM, AND THE VASCULATURE, ALL IPS-DERIVED ISOGENIC, WHICH CAN ALSO TALK TO THE PULMONARY EDEMA ASPECT.

IMPORTANTLY, BECAUSE THESE ARE IPS-DERIVED, IT ADDRESSES THE CONCERN THAT ONE HAS. THESE ARE PATIENT-SPECIFIC LUNG ORGANIDS. IN THE PIPELINE WE ARE MAKING LUNG ORGANIDS FROM A VARIETY OF RACES, INCLUDING AFRICAN-AMERICANS AND CAUCASIANS, FROM MALE VERSUS FEMALE, FROM A VARIETY, PARTICULARLY OF THE HLA MUTATION, THAT HAS BEEN DOCUMENTED TO BE MOST SUSCEPTIBLE TO SARS-2 INFECTION. IT PROVIDES A DEVELOPMENTAL PROFILE SO WE CAN FIGURE OUT WHY IS IT THAT KIDS MAY BE LESS VULNERABLE, BUT WHEN DO THEY BECOME VULNERABLE?

THESE ARE THE ONLY LUNG ORGANIDS OF THIS KIND IN THE WORLD'S LITERATURE. BUT AS YOU CAN IMAGINE, IF IT COMES OUT OF THIS, CALIFORNIA WOULD BE THE LEADER IN THE ONLY AUTHENTIC SYSTEM PROVIDING A TOOL FOR SCREENING, NOT ONLY THESE DRUGS, BUT OTHER FUTURE KINDS OF THERAPIES IN ADDITION TO SOME

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MORE ESOTERIC ANSWERS, LIKE, WHAT IS THE MECHANISM OF ACTION OF THE VIRUS? WHAT CELLS DOES IT REALLY BIND TO? WHAT'S THE MECHANISM OF ACTION OF A DRUG?

WE WERE CRITICIZED FOR ONLY TWO ASPECTS. ONE, THE BANDWIDTH. AT THE TIME WE ONLY HAD THREE PEOPLE WORKING IN THE LAB. NOW WE HAVE 12, MOSTLY FROM VOLUNTEERS WHO ARE SO ENTHUSIASTIC ABOUT DOING THIS, THAT THEY WANT TO BE PART OF THIS EFFORT.

AND THEN PRELIMINARY DATA, NOT ON THE INTEGRITY AND THE VALUE OF THE SYSTEM, BUT SPECIFICALLY WITH SARS-2 INFECTION. AND THEY WERE ASKING FOR ANY VIRAL DATA FOR ANY VIRUS. WELL, IN FACT, NOT ONLY DO WE HAVE SOME PROMISING DATA WITH THE PSEUDOVIRUS, BUT THE LUNG ORGANOID SYSTEM WAS DEVELOPED INITIALLY FOR BEING GENE MODIFIED WITH A LENTIVIRUS, LENTIVIRAL MEDIATED GENE TRANSFER, WHICH, OF COURSE, SHOWS THAT IT IS INFECTIBLE WITH A VIRUS.

MS. BONNEVILLE: DR. SNYDER, YOUR THREE MINUTES HAVE PASSED.

DR. SNYDER: CAN I SAY ONE MORE THING OR IS THAT --

MR. SHEEHY: QUICKLY PLEASE.

DR. SNYDER: OKAY. I JUST WANTED TO MAKE ONE COMMENT FROM ONE OF THE REVIEWERS THAT SAID,

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GIVEN THAT THEY, MEANING OUR GROUP, ARE AN EXPERIENCED LAB WITH GOOD EXPERTISE AND THERE WAS ENTHUSIASM ABOUT MANY ASPECTS OF THE AWARD, I LEAN TOWARDS GIVING THEM AN OPPORTUNITY. AND I WOULD THINK THAT IF THIS WAS UNFUNDED, DISC2 IS THE PERFECT MECHANISM FOR ALLOWING US TO DO THIS.

MR. SHEEHY: THANK YOU, DR. SNYDER.

IS THERE ADDITIONAL PUBLIC COMMENT TO THIS MOTION? MS. BONNEVILLE, COULD YOU CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

DR. DURON: I'M SORRY. ARE WE VOTING WHETHER OR NOT TO MOVE THIS FORWARD? I'M NOT SURE WHAT THE VOTE IS.

MR. SHEEHY: I'M SORRY, MS. DURON. WE ARE VOTING TO NOT FUND ANY OF THE REMAINING APPLICATIONS, WHICH ARE THE ONES THAT WERE IN THE UNFUNDABLE SCORING RANGE. SO THESE WERE THE ONES THAT WERE NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP. SO THESE ARE THE ONES NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP. AND SO IN ORDER, WE NEED SPECIFICALLY NOT TO FUND.

DR. PRIETO: MR. CHAIR.

MS. BONNEVILLE: FRANCISCO HAD A QUESTION AS WELL.

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DR. PRIETO: JUST TO CLARIFY MY UNDERSTANDING WOULD BE THAT IF WE WANTED TO MOVE ANOTHER APPLICATION BACK INTO THE FUNDABLE RANGE, YOU WOULD HAVE TO VOTE NO ON THE CURRENT MOTION, AND THEN WE WOULD NEED A SUBSTITUTE MOTION TO MOVE THAT APPLICATION UP, VOTE ON THAT MOTION, AND THEN RETURN TO THIS MOTION. IF YOU WANT TO NOT MOVE ANYTHING AND PROCEED AS ORIGINALLY WE WERE GOING, THEN YOU WOULD HAVE TO VOTE YES ON THE CURRENT MOTION.

MR. SHEEHY: THAT'S CORRECT. AND I JUST WOULD NOTE THAT WE'RE REVIEWING CONSTANTLY NOW. SO APPLICATIONS CAN BE RESUBMITTED AND RE-REVIEWED AS WE JUST DID WITH DR. WONG'S APPLICATION IN A FAIRLY EXPEDITIOUS PERIOD OF TIME. SO CONCERNS COULD BE ADDRESSED IN THAT PERIOD. BUT, ANYWAY, SO THAT'S THE MOTION. MS. BONNEVILLE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

DR. DURON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVE MARTIN.

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DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA
PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT. AL
ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD. JONATHAN
THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: DIANE WINOKUR. LET ME
SEE. IS DIANE GIVING ME A THUMBS UP? DIANE. I
COULDN'T RECORD YOUR VOTE.

MS. WINOKUR: YES.

MS. BONNEVILLE: THANK YOU SO MUCH. THE
MOTION CARRIES.

MR. SHEEHY: THANK YOU. CHAIRMAN THOMAS,

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THAT CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE.

CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. THANK YOU FOR ALL THE PARTICIPANTS IN THAT DISCUSSION. WE NOW, I BELIEVE, HAVE APPROVED OUR SEVENTH, EIGHTH, AND NINTH COVID-RELATED PROJECT, AND WE WILL UNDOUBTEDLY HAVE MORE INTERESTING ONES TO COME IN THE FUTURE. SO THANK YOU.

WE ARE AT THE STAGE OF THE AGENDA FOR GENERAL PUBLIC COMMENT ON ANY ITEMS WHATSOEVER. DO WE HAVE ANY PUBLIC COMMENT?

MS. BONNEVILLE: WE DO NOT.

CHAIRMAN THOMAS: HEARING NONE, THAT CONCLUDES --

DR. DURON: J.T., CAN I MAKE A COMMENT PLEASE?

CHAIRMAN THOMAS: CERTAINLY.

DR. DURON: THANK YOU. I GUESS IN LISTENING TO DR. SNYDER, MY HEAD MOVES -- MY HEART MOVES TOWARDS THINKING ABOUT WHAT HE SAID AS OPPOSED TO MY HEAD KNOWING WHAT THE HECK YOU'RE TALKING ABOUT. BUT I WAS LOOKING AT THE NO VOTES, AND THERE WERE LIKE 11 NO VOTES ON THIS PROJECT. AND SO PART OF ME WANTS TO SUPPORT HIM COMING BACK, BUT WITH 11 NO VOTES, I DON'T KNOW WHAT CHANCE HE HAS. SO I'M

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JUST SAYING THAT I GET TORN BETWEEN THE EMOTIONAL ASPECT OF WANTING TO SUPPORT SOME AND GIVE IT A TRY VERSUS THE SCIENCE SAYS IT'S NOT READY FOR PRIME TIME.

SO I APPRECIATE ALL OF YOUR GUIDANCE ON THIS. IT JUST ONCE IN A WHILE I LOOK TO TAKE A FLIER ON THIS. LET'S DO THIS. BUT I WILL FOLLOW YOUR GUIDANCE.

CHAIRMAN THOMAS: SO I JUST WOULD LIKE TO CONCUR WITH MR. SHEEHY'S COMMENTS ON THIS. AND THANK YOU FOR THAT, MS. DURON. THIS IS A MATTER, ACCORDING TO DR. SNYDER, OF A COUPLE OF CRITIQUES THAT WERE SPECIFICALLY MADE WHICH HE HAS ADDRESSED, AND IN DOING THAT HE WAS WELCOME TO RESUBMIT AND HAVE THOSE CRITIQUES REEVALUATED. WE HAVE THAT PROCESS DONE ALL THE TIME. AND THIS IS A VERY SHORT TERM FOR DR. SNYDER AND OTHERS TO ADDRESS THE CONCERNS REFERENCED IN THE COMMENTS.

OKAY. SO HEARING NO OTHER COMMENT BY MEMBERS OF THE BOARD OR THE PUBLIC, THANK YOU, EVERYBODY. PLEASE CONTINUE TO STAY SAFE AND HEALTHY. AND WE WILL BE RECONVENING SHORTLY FOR THE NEXT ROUND OF DISCUSSION ON THESE GRANTS. THANKS VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT 2:01 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS VIA ZOOM BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS EMERGENCY MEETING HELD ON MAY 29, 2020, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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